UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,072	07/03/2003	David Lewis	239775US0DIV	3477

22850 7590 06/21/2005

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/612,072	LEWIS ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the amendments and remarks filed on 03/22/05. Claims 11, 19 and 26 were amended and no claims were cancelled or added. Accordingly claim 11-32 remain pending.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 11, 14-15 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rovee et al (4,185,100) in view of Hettche et al (5,415,853) or alternatively in view of Cutie (5,891,419).

Rovee teaches a pharmaceutical composition for topical treatment of skin disorders comprising an anti-inflammatory corticosteroid. The suitable corticosteroids include triamcinolone acetonide (col. 2, lines 62-68). The solvents include ethanol and propylene glycol (col. 3, lines 25-26 and tables A and F). The suitable anti-oxidants include butylated hydroxytoluene (col. 4, lines 41-44; col. 5, lines 45-47). Table F discloses propellant for aerosol formulations. Rovee lacks specific disclosure on HFA propellants.

Hettche et al teach aerosol compressed gas packages containing a polyoxyethylene glyceryl oleates and a propellant. Hettche et al states that "since the

position of the "ozone theory" there has been a search for liquid gases which can serve as propellants and which are neither combustible, nor liable to break down ozone and which are moreover, not harmful to health. For some time, non-chlorinated fluorohydrocarbons such as (TG 134a) and (TG 227) have been used".

Cutie teaches aerosol formulations for oral inhalation containing flunisolide dispersed in HFC 134a and/or HFC 227, and metered dose inhalers suitable for delivering such formulations. Said formulations contain small amounts of ethanol (col. 3, lines 39-42) and antioxidants (col. 4, line 43). Cutie discloses that said formulations are suitable for treating respiratory disorders such as bronchial asthma (col. 3, lines 43-45).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general formulations of Rovee et al to have looked in the art for specific propellants which are better suited for environments and patients, as taught by Hettche et al or Cutie, with a reasonable expectations of successfully preparing safe and effective aerosol preparations. It is well known in the art, as shown by Hettche, Cutie and others that over the past decade or so CFC propellants have been replaced by HFA propellants, and thus use of HFA propellants is not a support for patentability.

Claims 11, 15-23, are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al (WO 9834595).

Keller teaches medical aerosol formulations which comprise an active agent, a propellant mixture, a cosolvent and other optional additives. The suitable active agents include budesonide available in an amount of from 0.001 to 5% by weight (page 16, line 2 and page 17, line 30 to page 18, line 2). The preferred cosolvents, which are particularly advantageous in the solution formulations, include ethanol and propylene glycol which are generally available in an amount of 0.1 to 30% by weight (page 19, lines 11-28 and claims). The propellants include HFA 134a and HFA 227, generally available in an amount of at least 64% (claim11). Keller discloses use of vitamin E in the formulation (as an active agent).

Keller also discloses that the active agent can be used in a pharmaceutically acceptable salt form (page 17, lines 26-29).

Although Keller does not disclose use of vitamin E as an antioxidant however, Keller discloses their use in the formulation. Vitamin E is a known antioxidant and thus preparing such formulations would have been a logical extension of the teachings of Keller, and that said modifications would have been obvious to one of ordinary skill in the art.

Claims 11, 16-19, 21-23, 26, 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cutie (5,891,419).

Cutie teaches aerosol formulations for oral inhalation containing flunisolide dispersed in HFC 134a and/or HFC 227, and metered dose inhalers suitable for delivering such formulations. Said formulations contain small amounts of ethanol (col. 3, lines 39-42) and antioxidants (col. 4, line 43). Cutie discloses that said formulations are suitable for treating respiratory disorders such as bronchial asthma (col. 3, lines 43-45).

Claims 12-15, 20, 24-25, 27, 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cutie (5,891,419) in view of Radhakrishnan et al (5,192,528).

Cutie, discussed above, lacks disclosure on specific antioxidants and budesonide.

Radhakrishnan teaches corticosteroid inhalation treatment methods of delivering a therapeutic dosage of corticosteroid drug to the lungs. The corticosteroids include flunisolide, budesonide, etc (col. 4, lines 14-25). The formulation (described in example 1) is formed by adding alpha-tocopherol with the corticosteroid and lipids (col. 4, lines 34-37).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general formulations of Cutie for inhalation administration of corticosteroids and antioxidants, to have looked in the art for more specific antioxidants suitable for combination with corticosteroids for inhalation, as taught by Rafhakrishnan, with reasonable expectations of successfully preparing stable and effective formulations. Furthermore it would have been obvious to a person of ordinary

skill in the art to have chosen other corticosteroids such as budesonide or other antioxidants such as ascorbyl palmitate.

Double Patenting

The provisional rejection of claims 11-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/244,519 is maintained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed on 03/22/05 have been fully considered but they are not persuasive.

Applicant argues that Rovee et al teaches CFC 12/114 propellants and not the HFA propellants of the instant claims. The amendments necessitated a new rejection based on Rovee et al in view of Hettche et al or alternatively Cutie, as stated above. It is well known in the art, as shown by Hettche, Cutie and others that over the past decade or so CFC propellants have been replaced by HFA propellants, and thus use of HFA propellants is not a support for patentability.

Applicant argues that Keller et al is disclosing a fluorinated alkane propellant and carbon dioxide. Applicant is referring to Examples 4 and 5 which disclose a steroid in the presence of an HFA/CO2 propellant. This is not commensurate with the scope of the claims. Instant claims are formulation claims which use the open language of

"comprising". Use of CO2 in the instant formulations is not excluded. Thus it is considered that Keller reference is meeting all the limitations of the rejected claims.

Applicant argues that in Cutie's reference ethanol is "to prevent dissolution" of the flunisolide. Applicant further states that "this disclosure is directly at odds with the present invention wherein a cosolvent (e.g. ethanol) is used to dissolve the active ingredient in the propellant". This is not commensurate with the scope of the claims. Instant claims are drawn to a formulation *comprising*..... The claim does not specify the form of the formulation. There is no requirement for the active agent to be *dissolved*. Thus it is considered that Cutie, disclosing suspensions of flunisolide, ethanol, HFA and other ingredients meet all the limitations of the instant claims.

Applicant argues that Radhakrishnan et al does not compensate for the deficiencies of Cutie. This is not persuasive because as stated in the rejection, Cutie lacks specific disclosure on the use of specific antioxidants, and Radhakrishnan teaches the specific antioxidants in similar formulations.

With regard to the double patenting rejection over the copending application, U.S. 10/244,519, Applicant argues that if the co pending application is not yet in condition for allowance, the said rejection should be with drawn. Applicant is correct and the provisional double patenting rejection in (the two co-pending applications) the application placed in condition for allowance first, will be withdrawn.

InterferenceApplicant's remarks regarding U.S. application 10/176,851 (publication No. 20030053957 A1) are correct. The said application has been abandoned and thus there is no need for an interference.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Mina Haghighatian
June 15 2005